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# NOTICE OF ALLOWANCE AND FEE(S) DUE

23117

7590

02/28/2008

NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203

**EXAMINER** RAGHU, GANAPATHIRAM ART UNIT PAPER NUMBER

1652 DATE MAILED: 02/28/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,834	01/30/2006	Hisashi Narimatsu	GRT/159-89	5006

TITLE OF INVENTION: GLYCOSYLTRANSFERASE, NUCLEIC ACID ENCODING THE GLYCOSYLTRANSFERASE AND METHOD OF TESTING

CANCERATION USING THE NUCLEIC ACID

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	05/28/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current **SMALL ENTITY status:** 

A. If the status is the same, pay the TOTAL FEE(S) DUE shown

B. If the status above is to be removed, check box 5b on Part B -Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

## Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

(571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 23117 7590 02/28/2008 Certificate of Mailing or Transmission NIXON & VANDERHYE, PC I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/539,834 01/30/2006 Hisashi Narimatsu GRT/159-89 5006 TITLE OF INVENTION: GLYCOSYLTRANSFERASE, NUCLEIC ACID ENCODING THE GLYCOSYLTRANSFERASE AND METHOD OF TESTING CANCERATION USING THE NUCLEIC ACID APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1440 \$300 \$0 \$1740 05/28/2008 **EXAMINER** ART UNIT CLASS-SUBCLASS RAGHU, GANAPATHIRAM 1652 435-097000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this fo Advance Order - # of Copies \_ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/539,834	01/30/2006	Hisashi Narimatsu	GRT/159-89	5006	
23117 7.	590 02/28/2008		EXAM	INER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR			RAGHU, GANAPATHIRAM		
			ART UNIT	PAPER NUMBER	
ARLINGTON, VA	X 22203		1652		
			DATE MAILED: 02/28/200	8	

# **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)				
	10/539,834	NARIMATSU ET AL.				
Notice of Allowability	Examiner	Art Unit				
	GANAPATHIRAMA RAGHU	1652				
The MAILING DATE of this communication appea.  All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313  1. ☑ This communication is responsive to 01/23/08.	(OR REMAINS) CLOSED in this apport or other appropriate communication (GHTS. This application is subject to	plication. If not included will be mailed in due course. <b>THIS</b>				
2. ☑ The allowed claim(s) is/are <u>13,14 and 31-34</u> .						
<ul> <li>3.  Acknowledgment is made of a claim for foreign priority ur</li> <li>a)  All b)  Some* c)  None of the:</li> <li>1.  Certified copies of the priority documents have</li> <li>2.  Certified copies of the priority documents have</li> </ul>	been received.					
3.  Copies of the certified copies of the priority do	3. Copies of the certified copies of the priority documents have been received in this national stage application from the					
International Bureau (PCT Rule 17.2(a)).						
* Certified copies not received:						
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.						
<ol> <li>A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give</li> </ol>						
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	st be submitted.					
(a) including changes required by the Notice of Draftspers	on's Patent Drawing Review ( PTO-	948) attached				
1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date						
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date						
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t						
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.						
Attachment(s) 1. ☑ Notice of References Cited (PTO-892)	5.	Patent Application				
2. Notice of Draftperson's Patent Drawing Review (PTO-948)	6. ☐ Interview Summary					
3. X Information Disclosure Statements (PTO/SB/08),	Paper No./Mail Date 7. ⊠ Examiner's Amendment/Comment					
Paper No./Mail Date <u>See Continuation Sheet</u> 4.  Examiner's Comment Regarding Requirement for Deposit of Biological Material	_	ent of Reasons for Allowance				
	9. 🔲 Other					

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 06/17/05; 10/11/05; 10/11/06;

A request for continued examination under 37 CFR 1.114, including the fee set forth in

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37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible

for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been

timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR

1.114. Applicant's submission filed on 01/23/08 has been entered.

In response to the Final Office Action on 07/23/2007 applicants' filed a response

received on 01/23/08. Said response amended claims 13, 14, 24 and added new claims 31-34.

Thus, claims 13, 14, 24 and 31-34 are pending in the instant Office Action and are now under

consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Claims 14, 33 and 34 are directed to an allowable product. Pursuant to the procedures set

forth in MPEP § 821.04(B), claims 13, 24, 31 and 32 directed to the process of making or using

an allowable product, previously withdrawn from consideration as a result of a restriction

requirement, 04/16/2007 hereby rejoined and fully examined for patentability under 37 CFR

1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have

been rejoined, the restriction requirement as set forth in the Office action mailed on

06/01/2006 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to

the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or

divisional application is anticipated by, or includes all the limitations of, a claim that is allowable

in the present application, such claim may be subject to provisional statutory and/or nonstatutory

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double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## **Priority**

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a 371 of PCT/JP03/17030, filed on 12/26/2003 and claims priority to Japanese Application JAPAN 2002-38075 filed on 12/27/2002 and a certified copy of English translation has been provided on 01/23/08 for the Japanese Application 2002-38075.

## Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/17/05, 10/11/05 and 10/11/06 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the IDS statement.

### **EXAMINER'S AMENDMENT**

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Gary Tanigawa on 02/20/2008.

Art Unit: 1652

The application has been amended as follows:

### In the Claims

Please replace the claims with the marked-up set of claims provided by the applicants' representative Gary Tanigawa on 02/20/2008 and attached herein along with the action

## Allowable Subject Matter

Claims 13, 14 and 31-34 are allowed.

The following is an examiner's statement of reasons for allowance: Following a diligent search it was determined that the prior art neither teaches nor suggests an isolated polypeptide of SEQ ID NO: 2 or SEQ ID NO: 16 with  $\beta$ 1,3-N-acetyl-D-glucosaminyltransferase activity. The closest prior art to SEQ ID NO: 2 or 16 of the instant application is Conklin et al., (US Patent No.: 6416988), discloses polynucleotides and encoding polypeptides having 99.8% sequence homology to SEQ ID NO: 2 and 16 of the instant invention. The polypeptides of the instant invention differ from the prior art wherein SEQ ID NO: 2 has an amino acid residue "S" at position 137 and SEQ ID NO: 16 has an amino acid residue "S" at position 112. The isolated polypeptides with SEQ ID NO: 2 or 16 of the instant application appears to be a natural single nucleotide polymorphism (SNP) of a gene encoding  $\beta$ 1,3-N-acetyl-D-glucosaminyltransferase activity and therefore would not have been obvious to one skilled in the art to change/mutate the specific amino acid residues as reported for SEQ ID NO: 2 or 16.

Any comments considered necessary by applicant must be submitted no later than the payment of issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Application/Control Number: 10/539,834

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D. Patent Examiner Art Unit 1652 Feb. 08, 2008.

/Rebecca E. Prouty/ Primary Examiner, Art Unit 1652